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# Participant Recruitment to a Primary Dental Care Trial – A Survey of Facilitators and Barriers

## Abstract

**Objective:** To identify reasons behind a lower than expected participant recruitment rate within a multi-centre paediatric primary dental care randomised controlled trial (RCT).

**Subjects (materials) and methods:** An online survey, based on a previously published tool, consisting of both quantitative and qualitative responses, completed by staff in dental practices recruiting to the RCT. Ratings from quantitative responses were aggregated to give overall scores for factors related to participant recruitment. Qualitative responses were independently grouped into themes.

**Results:** 39 anonymous responses were received. There was general agreement between quantitative and qualitative responses. Main facilitators related to the support received from the central research team and importance of the research question. The main barriers related to low child eligibility rates and the integration of trial processes within routine workloads.

**Conclusions:** These findings have directed strategies for enhancing participant recruitment at existing practices and informed recruitment of further practices. The results help provide a profile of the features required of practices to successfully screen and recruit participants. Future trials in this setting should ensure that the research being conducted addresses a question of interest to the practices, and that trial processes are as streamlined as possible. Research teams should actively support practices with participant recruitment and try to ensure they maintain the enthusiasm of the entire practice team.

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## Introduction

The “Filling Children’s Teeth - Indicated Or Not” (FiCTION) trial is a Primary Care-based multi-site, three-arm, parallel group, patient-randomised RCT (Trial Registration - ISRCTN77044005).<sup>1</sup> It aims to determine which approach to the management of carious primary teeth is the most successful in the context of primary dental care in the UK. All trials start with a fixed recruitment period - FiCTION started with 12 months- however, the rate of participant recruitment was lower than anticipated. The STEPS study which investigated strategies for trial enrollment and participation, found only 31% of randomised controlled trials (RCTs) recruited to time and target.<sup>2</sup> A review by Treweek and colleagues recognised that achieving recruitment is an issue in medical research, and that knowledge on how to increase recruitment at sites participating in a trial is currently lacking.<sup>3</sup> This challenge was further reinforced by a recent survey of Clinical Trials Units Directors where “research into methods to boost recruitment in trials” was found to be their highest research priority.<sup>4</sup> The FiCTION trial involves the recruitment of children, which the RECRUIT study found to be even more challenging.<sup>5</sup> Additionally, these children are being recruited by more than 50 general dental practices across 5 regional centres over the UK. These general dental practices were already busy and few of them had participated in research before.<sup>6,7</sup>

Why attempt such a challenge? For the primary care dentist faced with the prospect of managing a child with caries, there is little direct evidence to guide their decisions. Existing evidence has shown that a number of approaches to the treatment of carious primary teeth can be successful.<sup>8</sup> However, very few trials have compared the relative merits of these differing approaches in the context of primary dental care - the setting

where children in the UK routinely receive their dental care. Despite improvements in child oral health, dental caries continues to affect 27.9-33.0% of 5-year olds in the UK,<sup>9,10</sup> and this is a disease that can progress to cause excruciating pain and infection.<sup>11</sup> The lack of clear answers to guide a dentist's decisions is reflected in the finding that only 10% of decay in 5-year olds is currently restored (ft/dmft) in the UK.<sup>9,10</sup>

To enable the research question for FiCTION to be answered, the trial needs to recruit sufficient numbers of children. With few large dental RCTs undertaken and even fewer in primary dental care, little guidance was available on how barriers to participant recruitment could be addressed in this context. It was important to ensure that, as a research team, we were doing everything possible to support FiCTION practices with participant recruitment. To understand the barriers to recruitment in medical studies, Kaur *et al.* developed a survey tool investigating recruitment in multi-centre medical RCTs.<sup>12</sup> Using this tool, our aim was to identify reasons for FiCTION's lower than predicted participant recruitment rate and develop practical strategies to support practices in maximising future participant recruitment.

## Methods

The Kaur *et al.* survey tool was modified to reflect the context of the FiCTION trial; the major contextual themes being the dental practice setting, the primary care environment and recruitment of child participants.<sup>12</sup> This modification process was undertaken by a team comprising; two Clinical Chief Investigators, the Senior Trial Manager and the Clinical Researcher and incorporated their experience and observations of participant recruitment in FiCTION. The Delphi Technique approach was used to modify the survey.

The survey tool was web-based with quantitative and qualitative sections.<sup>13</sup> For the quantitative section, respondents were presented with a six point Likert scale, -3 for a strong barrier, to +3 for a strong facilitator (no 0 score), and were asked to rate 41 factors identified in the Delphi process. These factors were grouped into six categories; Trial Features (9 factors), Practice Administration (9 factors), Child/Parent Traits (12 factors), Practice Team (10 factors), Family Information and Consent (5 factors) and FiCTION Research Team (5 factors). Factors that respondents had not experienced or considered not applicable to the recruitment process were rated as N/A.

The qualitative section contained five free-text boxes with open questions.

Respondents were encouraged to express their experiences and to make suggestions to improve participant recruitment.

For the analysis of the quantitative section, a summary score for each of the 41 factors was calculated by totalling the number and strength of responses. A score of “7” could be achieved if 3 respondents rated a factor “+3” and one respondent rated it “-2”.

These summary scores for each factor were placed in ranked order, and factors scoring a summary score of  $> +3$  were considered facilitators, factors scoring  $< -3$  were considered barriers and those scoring between  $-3$  and  $+3$  were considered neutral factors.

For the analysis of the qualitative section, two investigators independently grouped the open responses into themes. The derived lists of themes and allocation of responses were compared and any areas of disagreement resolved through discussion and mutual agreement (NI and AK).

## Results

There were 39 individual responses, which are broken down by the geographical FiCTION centre and practice team role in Table 1; for comparison the number of recruiting practices in each area is also given.

### *Ranking of factors related to recruitment*

The overall scores that respondents gave to the 41 factors, categorised as Facilitators, Neutral and Barriers are shown in Tables 2-4. In order to determine the relative influence of the 6 factor categories, all factor scores were added together within each category. The cumulative scores of the categories were; FiCTION Research Team (267), Practice Team (141), Trial Features (121), Practice Administration (3), Family Information and Consent (-40) and Child/Parent Traits (-90).

### *Themes from free-text responses*

#### Factors considered to be important facilitators to recruitment?

The facilitators considered by the 11 respondents as being most important were:

- Support from central FiCTION Research Team. “Even though my recruitment numbers are small to date I have received excellent support and encouragement from the FiCTION trial team. There has not been undue pressure imposed as there is an understanding of our practice profile” - Site Lead (Scotland).
- Involvement of full practice team. “Strong practice team motivation and sheer number of invites coupled with parent willingness to participate” - Practice

Manager (Wales).

- Excitement of being involved in generation of new knowledge. “Staff motivation, keen to make a difference to the future of dentistry” - Site Lead (London).

#### How facilitators have or could be implemented?

Suggestions by 7 respondents to the implementation of facilitative factors were:

- Regular communication between central FiCTION Research Team and practices. “They have been implemented through regular email contact and especially with one to one phone discussion” - Site Lead (Scotland).
- Training and delegation of tasks amongst full practice team. “Giving responsibility of the trial to the correct staff” - Site Lead (London).
- Ensure appropriate resources are available. “Appeal to our better nature or increase the funding” - Site Lead (Wales).

#### Factors considered to be important barriers to recruitment?

The barriers considered by 23 respondents as being most important were:

- Low numbers of eligible children encountered. “Number of eligible patients - time taken for initial app(ointment), child gets bored” - Dental Nurse (Scotland).
- Families response to being invited to participate in research. “To (sic) much info that was sent to parents tended to frighten them off. Parents were more likely to attend during school holidays. The question about injections was the



question most likely to 'frighten' them off" - Site Lead (North East).

- Families ability to comprehend information about participating in research.  
Example - "Parents low level understanding" - Dentist (London).
- Families established preferences about dental treatment. "Parents/patients have a preferred treatment option. SSCs and no LA. Parents prefer dentist to make decision on best treatment option" - Site Lead (Scotland).
- The additional burden research places on the family. "Some eligible patients declined to take part because of the amount of paperwork involved" - Dental Nurse (North East).
- Ensuring that practices are appropriately and promptly reimbursed for work done. "Payment complex and not occurring" - Practice Manager (North East).

#### How barriers have or could be addressed?

Suggestions by 15 respondents as to how barriers could be addressed were:

- Additional efforts by practice to screen children. "We have taken on a number of patients between the ages of 3 - 8 in the last few months. Patient who did not respond to a recall reminder we followed up ideally with a phone call asking patient if they would like to make appointment. If we were unable to contact by phone we sent a follow up letter" - Dental Nurse (North East).
- Helping families understand the nature of the research. "Had to explain to parents what they received. Some were confused what it meant" - Site Lead

(North East).

- Utilising additional diagnostic tests to find eligible children. “Radiographs where appropriate when examining child patients” - Practice Manager (North East).

#### How could FiCTION be organised differently to improve recruitment?

Suggestions by 16 respondents as to how the trial could be organised differently to improve participant recruitment were:

- Practices actively supported by FiCTION Research Team. “Trial team very supportive. Parents very keen to be part of the trial” - Practice Manager (North East).
- Efforts by families and practice team is recognised, and involvement is a rewarding experience. “Children love it! Love the colouring in and merchandise” - Site Lead (North East). “More time for our practice to set up. More appropriate and adequate service support costs, costs for taking dental staff (not dentists) to training events reimbursed understanding the logistical problems of allocating time for collecting data/ consenting” - Site Lead (Yorkshire).
- Trial processes and paperwork simplified and streamlined. “Simplify initial visit, too much paperwork, takes too long” - Dental Nurse (Scotland).
- Focus recruitment efforts on groups likely to be willing to participate. “Regular attenders 'trusted' what we told them about the trial” - Site Lead (North East).

“To salaried services we would invite newly referred patients.” - Site Lead (Scotland).

- Eligibility criteria inclusive as possible. “Increase the age range.” - Dental Nurse (Yorkshire).

### *Strategies for maximising recruitment*

Based on the results of the survey, the following strategies have been adopted to maximise the remaining recruitment period:

- Alongside promotional merchandise already distributed for participating children, practices that were successful in monthly recruitment were offered FiCTION branded mugs along with a tea break set. This limited gesture of thanks, recognising additional efforts practices make towards recruitment, was aimed at developing a positive atmosphere of fun and community amongst the practice teams.
- Recruitment of additional practices to increase the pool of children available for screening. To maximise the likelihood of successful recruitment at these new practices the following steps were implemented:
  - The survey results formed the basis of open discussions with practices prior to committing to FiCTION, ensuring that newly recruited practices had as many of the positive features identified.
  - Delivery of training was modified to maximise the practice team included,

by delivering as much of it as possible within the individual practice.

Close support from the FiCTION Research Team was offered to these new practices, particularly during the initial stages of setting up the key administrative processes.

## Discussion

For successful participant recruitment to a RCT within a typical general practice environment, our experience is that the whole practice team must be motivated towards it. The importance of this is reflected in the survey results which suggest that practice teams who believe that their additional hard work is worthwhile and contributes to important research of substantive relevance to their working lives, will commit the necessary effort. Respondents rated the FiCTION research question as a facilitator and whilst this will help promote recruitment, it can only achieve so much. The FiCTION Research Team has limited direct influence on the established practice team dynamics, however, the results of the survey identifies the key avenues - communication, practice support, team training and gestures of thanks.

Communication between the practice team and the FiCTION Research Team is important even before a practice becomes fully involved. Whilst the local FiCTION Clinical Leads did utilise existing local knowledge and had discussions with practices prior to their involvement, there was no tool or exercise to formally evaluate a practice's ability to successfully recruit. This meant that any pre-existing issues at practices did not become apparent until recruitment was due to begin. This survey has helped to guide recruitment of additional practices, informing open discussions with interested practices prior to them becoming fully involved in an attempt to pre-empt

problems.

Once a practice is involved in FiCTION communication remains important. Sometimes difficulties are common across practices, so the FiCTION Research Team can act as an important information conduit. The survey highlighted numbers of eligible children as a barrier to recruitment. With the reported 27.9 - 33.0% of 5 year olds in the UK having obvious dental caries experience, it is initially counter-intuitive to suggest that this is a problem.<sup>9,10</sup> However, the distribution of caries in children is such that the obvious disease is carried by those with more severe disease, and, as a result, many of the “easy” recruits have been found to be ineligible due to pain/sepsis. The use of bitewing radiographs in children has been shown to improve the detection of caries before it becomes clinically obvious.<sup>14</sup> The FiCTION trial protocol emphasises the use of radiographs in line with the UK FGDP guidelines, however, the low level of utilisation of bitewings in children is a known issue in primary dental care.<sup>15,16</sup> Practices have commented that adherence to these radiographic guidelines improves detection of early lesions and hence eligibility rates for the trial and these comments have been conveyed across the trial by the FiCTION Research Team.

As well as allowing for the transfer of knowledge, good communication allows practices to bring issues to the attention of the FiCTION Research Team. For example, it is important that practices are reimbursed Service Support Costs (SSCs) in a timely and comprehensive manner. The Primary Care Trusts (PCTs), who had responsibility for such payments in England, were dissolved during the FiCTION recruitment period. Confusion amongst Clinical Commissioning Groups, intended to assume PCT

responsibilities, compounded the issue of payment of SSCs. Whilst the FiCTION Research Team was not directly responsible, we pursued payments on behalf of FiCTION practices and kept practices informed.

Along with assisting practices with some of the bureaucratic challenges they have faced, the FiCTION Research Team provides practical support, such as assisting practices with setting up administrative processes to begin participant recruitment. Delivering support and training within the practice itself continues to be a useful method to ensure knowledge of FiCTION permeates the whole practice team. Participant recruitment is particularly reliant on administrative tasks. In general, these administrative tasks are assigned to dental nurses, receptionists and practice managers and therefore it is important that training is provided to the entire practice team.

We recognise that the trial sits in competition with many other demanding tasks in primary dental care. To help ensure that the trial remains prominent in the minds of practices, beyond our regular communication with practices, we have developed some limited gestures of thanks including local competition between practices, along with challenges to win trial branded items such as tea / coffee mugs. Initial reports from practices suggest that these gestures are appreciated and useful, primarily in introducing an element of “fun” to the recruitment process, but also helping to keep trial recruitment prominent within the practice.<sup>5</sup> Once participant recruitment to FiCTION is successfully completed we intend to evaluate the impact of the strategies developed from this survey on the overall process of recruitment.

Along with the numbers of eligible children discussed above, the main barrier to

participant recruitment related to trial processes and paperwork. Trial processes are standardised across research for good reason,<sup>17</sup> but unnecessary complexity will sap motivation and every effort should be made to avoid overwhelming the practices. Prior to the main FiCTION trial a pilot rehearsal study was undertaken, which led to the refinement of many processes.<sup>18</sup> For most practices, FiCTION is their first experience of being involved in a research trial requiring development of new skills. With a number of larger clinical trials now being undertaken in primary dental care, hopefully a pool of research capacity is being built for the future.

This survey was developed to provide input to an ongoing recruitment process. There was no opportunity to undertake a piloting exercise to validate the questions and responses. It would have been interesting to investigate the recruitment issue from the perspective of families involved, but the practicalities precluded investigation of this area at present. In due course, this aspect will be investigated further as part of the qualitative component of the FiCTION trial itself. To encourage respondents to be open and honest about the recruitment process, no efforts were made to track completion to individual practices or team members, or to determine whether the response represented an individual or collective opinion. This has meant that it has been impossible to calculate an overall response rate.

Undertaking this scale and complexity of RCT in the primary dental care setting is a novel experience and has highlighted the unique challenges this environment presents. However, if we are to meet the demand for RCTs to answer these research questions, fundamentally relevant to the practicing clinician, then it is crucial that we develop an

understanding of how to successfully engage with practice teams when undertaking research in this setting. Hopefully, the themes identified here will aid future trialists in identifying and considering the particularly relevant recruitment-related issues before undertaking trials in the primary dental care setting.

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## References

1. Innes NP, Clarkson JE, Speed C, Douglas GV, Maguire A. The FiCTION dental trial protocol -- filling children's teeth: indicated or not? *BMC Oral Health*. 2013 Jun 1;13(1):25.
2. Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, et al. Recruitment to randomised trials: strategies for trial enrollment and participation study. The STEPS study. *Health Technol Assess Winch Engl*. 2007 Nov;11(48):iii, ix–105.
3. Treweek S, Pitkethly M, Cook J, Kjeldstrøm M, Taskila T, Johansen M, et al. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database Syst Rev*. 2010;(4):MR000013.
4. Smith CT, Hickey H, Clarke M, Blazeby J, Williamson P. The trials methodological research agenda: results from a priority setting exercise. *Trials*. 2014 Jan 23;15(1):32.
5. Shilling V, Williamson PR, Hickey H, Sowden E, Smyth RL, Young B. Processes in recruitment to randomised controlled trials of medicines for children (RECRUIT): a qualitative study. *Health Technol Assess Winch Engl*. 2011 Mar;15(15):1–116.
6. Innes NPT, Evans DJP, Clarkson JE, Foley JL. Obtaining an evidence-base for clinical dentistry through clinical trials. *Prim Dent Care J Fac Gen Dent Pract UK*. 2005 Jul;12(3):91–6.
7. Hopper L, Morris L, Tickle M. How primary care dentists perceive and are influenced by research. *Community Dent Oral Epidemiol*. 2011 Apr;39(2):97–104.
8. Ricketts D, Lamont T, Innes NPT, Kidd E, Clarkson JE. Operative caries management in adults and children. *Cochrane Database Syst Rev*. 2013;3:CD003808.



9. Davies G, Neville J, Rooney E, Robinson M, Jones A, Perkins C. National Dental Epidemiology Programme for England: oral health survey of five-year-old children 2012. London, UK: Public Health England; 2013 p. 36.
10. Macpherson L, Ball G, Conway DI, Edwards M, Goold S, O'Hagan P, et al. National Dental Inspection Programme 2012 - Report of the 2012 Detailed National Dental Inspection Programme of Primary 1 Children and the Basic Inspection of Primary 1 and Primary 7 Children. Edinburgh, UK: Scottish Dental Epidemiological Co-ordinating Committee; 2012 p. 32.
11. Finucane D. Rationale for restoration of carious primary teeth: a review. Eur Arch Paediatr Dent Off J Eur Acad Paediatr Dent. 2012 Dec;13(6):281–92.
12. Kaur G, Smyth RL, Williamson P. Developing a survey of barriers and facilitators to recruitment in randomized controlled trials. Trials. 2012;13:218.
13. Bristol Online Surveys (BOS) [Internet]. [cited 2014 Jan 8]. Available from: <http://www.survey.bris.ac.uk/>
14. Newman B, Seow WK, Kazoullis S, Ford D, Holcombe T. Clinical detection of caries in the primary dentition with and without bitewing radiography. Aust Dent J. 2009 Mar;54(1):23–30.
15. Faculty of General Dental Practitioners. Selection criteria for dental radiography. 3rd ed. London: Faculty of General Dental Practitioners, Royal College of Surgeons of England; 2013.
16. Taylor GK, Macpherson LMD. An investigation into the use of bitewing radiography in children in Greater Glasgow. Br Dent J. 2004 May 8;196(9):563–568; discussion 541.
17. The Medicines for Human Use (Clinical Trials) Regulations 2004 [Internet]. [cited 2013 Nov 17]. Available from: <http://www.legislation.gov.uk/ukxi/2004/1031/contents/made>
18. Marshman Z, Innes N, Deery C, Hall M, Speed C, Douglas G, et al. The management of dental caries in primary teeth - involving service providers and users in the design of a trial. Trials. 2012;13:143.

Table 1. Responses by FiCTION Centre and practice team role

FiCTION Centre (number of recruiting practices)	Total Number of Responses	Number of Responses by Practice Team Role			
		Site Lead / Principal Dentist	Dentist	Dental Nurse	Practice Manager
Scotland (n = 9)	11	4	2	3	2
North East England (n = 11)	8	3	0	3	2
Yorkshire (n = 7)	6	3	0	2	1
Wales (n = 4)	5	1	0	0	4
London (n = 9)	9	2	2	4	1
Totals (n = 40)	39	13	4	12	10

Table 2. Overall scores for factors rated as facilitators to recruitment

Category	Factor	Overall Score
6	Ease of ability to contact the FiCTION Trial Team	77
6	Clarity and frequency of communication from the FiCTION Trial Team	65
6	Frequency of evening meetings with other practices and local FiCTION Trial Team	56
6	Motivation of the FiCTION Trial Team	55
4	Importance of the particular research question	43
1	Publicity about the trial and merchandise provided by the trial team	40
2	Organisation of training day	38
4	Importance of research generally in clinical practice	36
1	Clinical equipoise	28
4	Motivation of practice team	27
4	Clinician attitude to involving patients in research	27
1	Patient inclusion criteria	24
1	Previous research experience	21
4	Presence of designated research nurse/practitioner within practice	19
1	Payments to practice	15
6	Payment of Service Support Costs	14
4	Research experience of practice team	11
2	Local research culture	9
5	Experience and training of clinical team in seeking consent	5
3	Childs'/parents' attitude towards taking part in a clinical trial	4
4	Clinician preference for particular treatment	4

Category Key – 1 = "Trial Features", 2 = "Practice Administration", 3 = "Child/Parent Traits", 4 = "Practice Team", 5 = "Family Information and Consent", 6 = "FiCTION Research Team"

Table 3. Overall scores for factors rated as neutral to recruitment

Category	Factor	Overall Score
4	Unfamiliarity in discussing research with patients	3
2	Time required for collection of clinical data (i.e. ICDAS)	1
3	Additional trial investigations for children/parents	0
4	Difficulty in approaching patients for consent	0
3	Childs'/parents' familiarity with the clinical treatments involved	-1
3	Childs'/parents' concerns about a treatment new to them	-2
3	Language or cultural barriers	-2
1	Seasonal variation in patient attendance	-3
5	Clarity in presentation of trial information	-3

*Category Key – 1 = "Trial Features", 2 = "Practice Administration", 3 = "Child/Parent Traits", 4 = "Practice Team", 5 = "Family Information and Consent", 6 = "FiCTION Research Team"*

Table 4. Overall scores for factors rated as barriers to recruitment

Category	Factor	Overall Score
1	Study protocol compared to usual clinical practice	-4
2	Time between training and opening recruitment at practice	-4
2	Time between setting practice up to opening recruitment	-5
3	Additional trial questionnaires for children/parents	-6
3	Childs'/parents' preference for a particular treatment	-8
2	Recruitment target	-9
5	Time and setting of consent seeking	-10
3	Additional travel/time for children/parents	-11
5	Social and emotional dynamics of trial discussion with parents and children	-11
3	Childs'/parents' attitude to treatment choice by random allocation	-14
3	Duration of trial and follow up	-20
5	Amount and complexity of trial information provided	-21
2	Time to complete administrative work related to the trial	-27
4	Clinical workload	-29
3	Number of eligible children	-30

*Category Key – 1 = "Trial Features", 2 = "Practice Administration", 3 = "Child/Parent Traits", 4 = "Practice Team", 5 = "Family Information and Consent", 6 = "FiCTION Research Team"*